recommendations. Unfortunately, in this economic environment, people stretch them out, they don't change them as often as they should, but what is the result to the tanner? Lower dosage. It doesn't mean an increased dosage, a lower dosage.

The tanner lies in a tanning bed on an acrylic shield. These acrylics deteriorate over time, so that they become less effective at transmitting UV as the bed goes through its properties, so once again, what happens? A lower dosage, not an increased dosage.

It is almost like with a car, you want to make sure the car is tuned properly, you change the oil, and so forth, it becomes a very well running engine. How often does everybody take their car to get a complete tune-up? Not as often, and certainly the economy may affect how often people do that.

So, keep this in mind, salon owners are stretching this time frame out further. I would like to say that everybody doesn't, they do it properly, they don't. So, it's a lower dosage that is going on, much less effective due to those two particular points.

Let's talk for a minute about the X/Y lamp

compatibility suggestion. I certainly understand the direction to harmonize with IEC standards. I think Joe brought up some of the concerns about trying to harmonize, sometimes it doesn't.

The X/Y issue had dictated I think lamps according to wattage. Understand that that ballast system that is driving the wattage has a direct reflect on what type of output it gives. Not all 100-watt lamps, 120-watt lamps, 180-watt laps are driven by the same type of corresponding ballast.

If a ballast that is meant for a 120-watt lamp, if it's only 100 watts, it doesn't deliver the true output of what you might think it would be, so you have to consider what is the operating system that is being used in.

The point is, too, for lamp compatibility, to make it easier--make it easier for people to change their lamps when it becomes the time, my gosh, all the different lamps, consider how many thousands of tanning beds that are out there, and they are not only in major metropolitan areas, they are out in the suburbs, out in the country, I mean it would be an unbelievable task to try and get people to understand we have two systems now, one for the current way we are looking at it, and one

for all the thousands of beds that are out there.

You talk about the homeowner. How often does the homeowner--that was a concern--how often do they rotate the lamps. Those lamps that are being used are typically 800 to 1,000 hour lamps. On a 20-minute session, that's 3,000 hours. A homeowner is not going to go ahead and change lamps that often. It may be for the life of the bed that they have, it is going to stay in that particular system.

The last comment I want to share with you is on the warning label, and we addressed it. I certainly understand your concerns. I look towards making things, I think you have to consider making things not so much of an absolute because what would constitute obtaining skin cancer, if you say it may cause skin cancer, certainly, there are a lot of different variables - your heredity, we talked about melanoma skin cancer, heredity plays a large role, but when you look at it, "it will cause," what type of exposure will cause it, when I lie in that bed once, I will get it, that is an absolute.

I think we have to be a little bit more flexible on that and consider it might, it may, it

is possible, but by saying it will without defining what exposure will give it to you, I think it is hard to fit.

In any case, I thank you for your time and I hope you take these comments into consideration.

Thank you.

DR. ROTHENBERG: Thank you very much.

Our next speaker is Rick Mattoon. Again, please identify your connection, if any.

MR. MATTOON: Thank you. My name is Rick Mattoon. I am actually representing two organizations here today. First of all, I am here as Director of the National Training Institute, which is a national training program for various industries. Our primary training program institutes a specific course for the operation of an indoor tanning facility.

Secondly, I am also here as Executive Editor of Looking Fit Magazine, which is an indoor tanning trade publication which circulates to 22,000 tanning facilities across the country every month.

To kind of consolidate the time here and move along quickly, I have prepared a statement there that I passed out during the last break, and

I am just going to read from it briefly and then be available for any questions or comments afterwards.

I am submitting the statement to the Committee in response to two of the recommendations by the Food and Drug Administration regarding proposed amendments to the U.S. performance standards for sunlamp products. Due to the time constraints of the Committee, I will not speak on all proposed changes, however, I would like to make several comments related to two of the proposals.

The first proposal is Warning Label Inclusion on all Promotional Material. Although I agree on the importance of consumer-based warning labels on any product that has the potential to cause harm if used improperly, I would remind the Committee to consider the principal intended target of a warning label on a tanning device. This label is primarily intended for the consumer using the device for tanning purposes.

The primary function of any warning label is to protect those who are least able to protect themselves, in this case, the tanning consumer. People most likely to misuse a product are not typically those who are about to invest $2,500 for a single tanning unit to $250,000 for an entire

tanning facility.

These individuals have typically researched the market, compared products, tested equipment in a salon setting, and have most likely participated in one of three nationally recognized indoor tanning certification programs that routinely cover the adverse effects caused by the misuse of a tanning device.

To require a legible reproduction of the warning statement required by 21 CFR 1040.20 to all catalogs, specification sheets and descriptive brochures, and any other purchasing information pertaining to each sunlamp product and ultraviolet lamp is simply overkill.

Let's keep the warning label on the equipment so the intended user can have access to this information and, at most, include a reproduction of the label in the operator's manual where it makes sense.

Let's ask this question. What is a label supposed to achieve? It is supposed to create awareness and give education. Research has shown that warning labels are most effective when it offers new information that is believable and that is targeted to the intended audience at an

appropriate time.

As executive editor of LOOKING FIT magazine, the indoor tanning trade publication, I can attest to the fact that warning labels within promotional advertising in publications like ours or within informational brochures is not only ineffective, it can also be financially restrictive to some companies.

Secondly, I would like to just quickly comment on the redefining of a manufacturer. The proposal that "any person engaged in the business of manufacturing, assembling, or modifying sunlamp products shall be construed as manufacturing under the act if the modification affects any aspect of the product's performance or intended function(s)" be deemed a manufacturer could and would be detrimental to the daily activities of more than 60,000 legitimate businesses across the U.S. that offer commercial tanning devices.

The FDA's revision for the definition of a manufacturer should be considered very carefully. Currently, most salon owners maintain and repair equipment themselves. Occasionally, maintenance or repairs go from routine to complex. The definition of a manufacturer must be detailed in great detail.

Even in aircraft maintenance, there are two definitions of "modification" during routine or major repairs. I have defined those in the handout as minor and major modifications which I think we can learn from.

Prior to redefining a manufacturer, we must clearly define repairs or modifications that do not "significantly" affect the structural integrity or intended output of a tanning device. This can be accomplished by working closely with manufacturers and, most importantly, salon owners who routinely service and repair their equipment. For a salon owner to unwittingly cross the line on manufacturer status would be a financial disaster from which most could not recover.

In conclusion, considering the common goals among agencies and industry, it is my wish that both groups work more jointly in developing and defining objectives that have the needs of the tanning consumer utmost in mind.

I appreciate this opportunity today to submit this statement to the Committee. I hope that this statement and my future submissions and interactions will assist the Committee in their work on these important topics.

Thank you.

DR. ROTHENBERG: Thank you very much.

Our next speaker is Donald Smith.

MR. SMITH: Good morning. My name is Donald L. Smith, UVR Research Institute in Tucson, Arizona. Both my trip here and the research that you will see here presented were funded by my wife and myself personally.

Let's take a look, if we could, at some information from the Freedom of Information Act that I filed a few years ago. FDA sent me a wide variety of information and over a 15-year period, which is the time during which the existing action spectrum has been in force, we had 84 complaints, which means about one complaint for every 100 million tanning sessions. That is an enviable FDA complaint history by any standard.

Now, part of the credit goes to the educational programs, the professionalism of the salon owners and the manufacturers, but much of the credit for this enviable complaint history has to go to FDA's Dr. David Lytle and his colleagues for having the courage and the foresight to develop a more protective erythemal action spectrum, the FDA EAS, rather than adopt the less protective CIE

action spectrum in 1985.

For your information, Dr. Lytle wrote a very reasoned letter to CIE explaining why that was rejected way back then.

Today, FDA is recommending adopting the same less protective action spectrum that was rejected by Dr. Lytle and his associates in 1985, a recommendation that will increase the erythemal risk of the American public who of their own free will choose to tan.

On the other hand, I recommend staying with the more protective FDA action spectrum because it decreases the erythemal risk of the American public who choose to tan.

In addition, FDA wants to adopt the totally unproven and very difficult, if not impossible, to understand X/Y ratio system for labeling sunlamps. I recommend improving the existing system and adopting an easy-to-understand Bin system.

Paradoxically and counterintuitively, FDA is recommending the less protective CIE, while I am recommending the most protective erythemal action spectrum in the world - FDA's own.

FDA is recommending an unproven and

difficult-to-understand system, while I recommend an intuitive and easy-to-understand system. At stake in this dispute between politics of global harmonization and science is the safety of the American public who choose of their own free will to tan in the professional indoor tanning salon.

Let's talk about the doctrine and what is sauce for the good is sauce for the gander. Companies that fall under FDA's jurisdiction have to provide proof of efficacy before they can market their products. Therefore, it seems to me that FDA should be held to the same or higher standards of proof before they can make changes.

TEPRSSC, like the NASA Safety Committee, have the responsibility to make sure that they provide adequate proof.

FDA not only provided inadequate proof, they provided no proof to support the changes from the more protective to the less protective. FDA has not conducted adequate studies, in fact, no studies that I am aware of, to show supporting adopting the non-melanoma skin cancer action spectrum.

For your information, the NMSC was originally incarnated for ozone depletion studies,

it is only now being used here. They haven't considered the needless confusion that will ensue, nor did they pay any attention to the absolutely overwhelming negative response that this X/Y system received in February of 2002. Instead, we are making these draconian changes for the politics of global harmonization.

Well, let's take a look at why the FDA is more protective. We have a broader 1.0 weighting factor used by FDA. CIE goes 280 to 298, FDA, 280 to 302 nanometers, and so the CIE is therefore 28 percent less protective.

Here is looking at it from 250 to 400. Let's take a look at it here from 280 to 320. It's this delta that was the genius, this is a fudge factor that Dr. Lytle and these people put in because the photon distribution here, it is weighted more heavily, so that's the first factor.

The second one was by choosing a lower threshold, 156 versus 200. It also applied another fudge factor. So, the theoretical difference therefore between the two action spectrum is 1 FDA to 1.5 CIE.

Well, the theory is good, but what happens in actual practice? Here are some studies I did

with lamps. The theoretical is 1.5. If you take a GE black light PUVA lamp, you see that it is 1.51. You can buy a black light lamp in any Home Depot, and it will come out about 1.52 to 1.53 and the relationship.

But as the UVB increases, there is a 1 percent high-intensity discharge high-pressure lamp. Here is a typical 20-minute, 3.5, and here is a 10-minute high UVB, so the ratio between the two action spectrum changes by the distribution of the photons in the UVB and the UVA two ranges.

So, FDA responded to this by changing the maximum allowable dose from 800 to 600 joules per meter. Well, that helped some, but there is still this discrepancy. Now, what does this mean?

If time doesn't permit, this chart sums everything up, and I ask you all to pay attention. Here is the theoretical, and so switching from the FDA to the CIE would mean a change that this bed that is going 20 now, would be allowed to go to 24, and it proves out in the theoretical.

So, the 1 percent range, we would be saying it's 20 today, 27 now; the typical bed 20 today, 30 minutes before, and here is this high UVB where you have a high burning power 10 today, 17

under this.

Now, in February 2002, ladies and gentlemen, a regulator from Europe said, made the statement at that meeting that 9 percent of the people in Europe that attended a tanning salon would sunburn. We pooh-poohed, thought it was heat flush or lotions or whatever, but after I plotted these out, if they are letting them go 17 or 20 minutes in a bed we have 10, then, maybe they are sunburning them, but we don't have this.

Once again, this chart clearly shows the wisdom of Dr. Lytle and his colleagues for us adopting it, it's fudge factors, but they have been very protective and they have stood the test of time. So, this chart shows it, and FDA has not run any studies to compare these things, so therefore they haven't seen these things.

Here, we see these things. Now, Ms. Miller presented some things, so now we have this 47 to 52, but these are ivory tower, folks. When you look at total irradiances that are possible, it is like putting one foot in hot water and another in a block of ice. On the average, it is going to come out okay, but total irradiance will never show you the photon distribution within the different

wavelengths.

Now, they are asking a totally unproven system with the X/Y ratio. To the best of my knowledge, this is not in place anywhere in the world. Still, testing a single lamp in a test stand does not tell you how to calculate exposure schedules. For that, you have to have a standard protocol for measuring the array of sunlamps, i.e., the sunbed.

So, we are going to have a mass amount of confusion that is going to simply adversely affect the tanning public. We have got to look at what this ideal system should be.

First of all, it has to be easy to understand by all segments, and believe me, clients ask questions about these. It has to be logical, intuitive, has to be easy and inexpensive, and it has to resolve these two issues of sunlamp compatibility and exposure schedules.

We talk in language of the beds. We have got 30-minute beds, 20-minute beds, 15, and so on. I proposed at this meeting a bin system, taking bins and the beds, so if we have 30-minute beds and 30-minute bins, and let's look at what it would mean on a 20-minute bed.

Simply said, if you have a 20-minute bed, you could use a lamp that has a TE time of from 17 to 30. Now, the existing system is plus or minus 10, why did I go down to 15? That is simply because if you take the manufacturing error and the testing area, we will never work within plus or minus 10 percent. Our allowances, we are going to be lucky to work with 15.

So, this is something I have explained it to hundreds of tanning salon owners, and they understand this immediately.

So, here is the proposed system that FDA has, which is ivory tower, and what I propose is common sense and easy to understand.

Now, this action spectrum is for squamous cell carcinoma in albino mice that were irradiated with a lot of different lamps, but the predominant one were FS-40s with UVC at high levels. It is not an action spectrum for doing our lamps, it was never intended that, as I said, it was intended for the ozone depletion.

Here is what it looks like, from 250 out to 400, but let's look at it here. Ms. Miller showed you a log plot, but that is what it looks like.

Now, ladies and gentlemen, I have 6,000 articles in my Notes File, I went through them all, and everything that has been published in the literature for the last 30 years says these are the wavelengths associated with the induction of squamous cell carcinoma. So, why would you use an action spectrum that devalues those very wavelengths? The answer is you wouldn't.

So, here is the more protective FDA, here is the less protective CIE, here is this non-melanoma skin cancer action spectrum they are asking you to bless, and this is the melanogenesis action spectrum according to Parish where we calculate the TM value.

So, what they are saying is they want to use one that is even weaker and have less power than the one we use for TM. So, this one won't fly.

Here is the FS-40, here are some other lamps, Xenon filtered, Xenon unfiltered, the FS-340, it was called the Q-Sun, and here, you can see the comparison when you look at the A and B here versus over here. These lamps are not reflective.

It might be helpful for you to see how

here is sunlight, the Xenon low pressure or high pressure/low pressure, and here is the filtered and the unfiltered lamps. So, if you look at it just for the A and the B classifications, you can see that the lamps used for these studies were not good.

The key thing here is consequently, in studies designed to understand skin biology after solar exposure, the use of these sunlamps may lead in misleading or even incorrect conclusions.

So, it is not an appropriate thing, and it is going to damage the industry, as has been mentioned, it's political, not scientific, it is simply to get the word "cancer" incorporated.

Ms. Miller didn't tell you, but me say I clarified it with her before the meeting, the Y/X's will be the power of that sunlamp to cause skin cancer, that's what it is. So, you need to think through what this is going to do to get liability insurance for vendors and salon owners.

Well, that is what they proposed on the warning label. Here is what I proposed in the letter. It is overexposure of ultraviolet irradiation that may cause this, not exposure. Furthermore, I suggested saying individuals taking

a medication or using a cosmetic product that may increase their sensitivity to ultraviolet radiation should check with their physician or pharmacist before tanning. That is on our standard informed consent form.

Individual with systemic lupus erythematosus, rosacea, or who have received medical treatment for a diagnosis of skin cancer should check with their physician before tanning. If they want to put physician/dermatologist in there, I have no problem.

You know, we worry about all these little things, but people who have lupus, who read on the web sites that UV irradiation is beneficial, they are talking about UVA-1, and they go in a bad blood spectrum, and it's damaging.

DR. ROTHENBERG: Please finish up.

MR. SMITH: The definition of manufacturer, the same thing I said to you folks last year, if you don't have a standard protocol for measuring performance, which is at the heart of this, then, you can't have a regulation that depends on it.

So, first, we need to get a standard protocol before this.

Let's talk about these lamps, and I want to go right to this. Here is a lamp that I ran, the standard low pressure. It isn't just high pressure things, the problem actually is more acute in the low pressure lamps with the eyewear, because here is the spectrum and here is the spectrum that you see here after I put the eyewear. This is the least protective eyewear.

You can see it gets rid of the mercury peak at 405, but it doesn't get rid of it all out here at 436 and at 550. So, now, if you look at this and plot it out, you can see that for the most part, and the average is 2.7 percent, and integrating it, and, Doctor, the question you asked before, you do have to integrate it by 5 nanometer increments, but we violate it here.

So, what we need to do is to ask people like Dr. David Sliney [ph] of the Army, is this--because it's very low levels--the fact that it violates this, is this meaningful, because keep in mind when you look at this, that here is the Hobson's Choice. If you restrict the ability of lenses that have more transmission, that they wear in these new beds that have a lot of controls, then, you tempt the people to remove their glasses

to see the controls where they are affected to this.

So, what we need to do is to find out is this amount of irradiance passing through here on these two mercury peaks, or, conversely, can the lamp manufacturers reduce this, so it isn't there.

Okay. Approve the revised label with the overexposures and the other. Instruct FDA to go back. We have got a lot more work to do before we can standardize the eyewear products, and we need to develop standard protocols for testing sunlamps and sunbeds before we can do any of these things.

Reject them to change from the more protective FDA erythemal action spectrum to the less protective CIE, adopt the unproven, politically motivated X/Y system, and work with us to improve the existing system and make protecting the American public, not global harmonization, their first priority.

Ladies and gentlemen, in my opinion, what we need to do is to put America first.

Thank you.

DR. ROTHENBERG: Thank you.

We have one additional speaker, Laura Edwards. Please again identify your organization.

MS. EDWARDS: I would like to thank the committee for the opportunity to speak. My name is Laura Saul Edwards. I am the Assistant Director of Federal Affairs with the American Academy of Dermatology Association, which represents 13,000 dermatologists nationwide.

I do not have any financial interest supporting my appearance here. Indeed, the sole concern of the Association is the public health concern. Based on that, the AADA's policy with respect to indoor tanning is--I am sure you are not surprised--we would like to see indoor tanning go away and have it completely banned, but in the absence of a ban, we do support having this industry highly regulated to protect the public's health to the greatest extent possible.

It was with that in mind that we gladly accepted the offer to meet with the FDA officials involved with this in June at Howard Cyr's invitation. It was a very productive meeting where our leaders on this issue learned more about how FDA approaches regulating the industry, and they learned about our clinical and scientific concerns with the industry.

So, we are also very appreciative of this

proposal. Priority to the Association is the warning label, Proposal No. 1. I was encouraged to hear around the table the concern, as well, with the language of "may" versus other suggestions for strengthening that label.

The AADA urges the committee to support strengthening the label, to please delete the word "may," replace it with "can" or "is known to cause cancer."

This is a scientific fact. This would just strengthen I think the public health concerns that I have heard the prior speakers mention, and if you would like to discuss this at greater length, I am pleased to comment on that.

As far as the other proposals included in this package, the AADA is considering them closely. They would be happy to provide additional comment to the committee and the CHRD, particularly Dr. Miller, as this proposal is developed. Our Environment and Drugs Committee is analyzing it.

At this time, I am going to close my comments. I will stay and be available for any questions that you might have. Again, thank you.

Committee Discussion

DR. ROTHENBERG: Thank you very much.

Do either Dr. Cyr or Sharon Miller have any comments that you would want to make at this time regarding our public presentations?

MS. MILLER: Yes. Where do I begin? There are several things mentioned by the speakers that I feel I should comment on. Basically, I would just like to say it was mentioned that harmonization for harmonization's sake may not be the way to go, and it is true that FDA has a federal mandate to harmonize with existing international standards, but also what is really driving us is to improve safety to the public. That is our main goal.

These international standards have been developed by a large panel of international experts, so we don't feel that they have been created foolishly or prematurely. This committee, the EIC Committee has been in existence for probably 15 years and consists of very well known experts in the field, people from academia, people from government-regulating bodies, so we don't think any of these recommendations have been taken lightly.

As far as some of the specific suggestions that were made, one person suggested that in the

warning label, we should specify that the injuries to the eye are only in the case of unprotected eyes. I feel that the way the label is worded, it says, "Ultraviolet radiation may cause injury to the eye and skin," and that's a true statement.

If you were saying sunlamp exposure may cause injury to the eye and skin, that might be true only in the case of the unprotected eye, but I think in the interest of keeping the label as short as possible, that it doesn't really add anything to say that it causes injury to the unprotected eye because if we tell people it causes injury or can cause injury to the eye, and wear the protective eyewear, I feel that that provides adequate instruction to the user.

Also, with regards to the warning label, someone suggested that we say not that exposure may cause, but that overexposure may cause skin cancer and skin aging, and so forth. We don't like the use of the word "overexposure" in that instance because overexposure is a very ambiguous term. An individual does not know what overexposure means to them, and they certainly won't know until the next day whether they have been overexposed, because the erythema will not show up until 24 hours later

approximately.

So, we prefer just to keep it at exposure.

Several people mentioned that some of our changes could cause detrimental financial, could have a financial impact on the industry, and as I mentioned before, FDA is required to do an economic impact analysis, so many of those considerations will be addressed during that analysis session.

A change in the action spectra may cause some problems for bookkeeping for the industry. It is true they have been using this action spectrum, they have experience with it, but we don't feel that with the state of computers and the ease of use of spreadsheets, that changing the action spectrum will prove that difficult.

As I say, it is already used in the FDA standard and I think it's just in the long run, will be simpler for everyone in this business to be using one action spectrum, and not two, one for the U.S. and one for the rest of the world.

It was also mentioned that our standard, that the proposals we are presenting here today are not in a line with what Health Canada has in their standard. We work very closely with people from Health Canada. They have made changes to their

standard probably in the past, I don't know, maybe six months ago.

Some of the changes we are presenting today are more recent developments in the international standard community, so that is why they are not in their standard, but we know from our discussions with them, that they do plan to go the same route that we go. They probably will be proposing the same changes in their standard in the near future.

Regarding Don Smith's presentation on the changing of the action spectrum, I think his presentation was a bit misleading because it is true the CIE action spectrum has lower relative effectiveness values in a portion of the spectral area, what is really important, though, I believe, is what the total dose is.

The numbers that he is showing you were comparing an MED of 156 to an MED of 200, but what is really important, in my mind, is that the maximum timer limit is still approximately 600 joules, and, in fact, that is lower than what is in the current FDA standard, which is 624 joules based on 4 MEDs.

If we go to 3 MEDs of the new level of

200, that will only be 600, so it is actually a lowering of the effective dose, and the effective dose is more important than the individual weighting values are giving to each region.

As I said, this action spectrum has been well tested on thousands of people all over the world to show that it is at least accurate in predicting erythema for different types of lamps.

As far as the rating system goes, I was a little confused by some of Don's remarks about the X/Y system being discussed in 2001 because this system was really just introduced in June of this year, so I don't know what he is referring to there.

But we don't think, once people get used to it, it will be that difficult to understand. As far as it being a liability for people for manufacturers or salon owners to have a cancer number, since we know that UV does cause cancer, we don't feel that having a number that represents the non-melanoma skin cancer action-weighted output really changes the situation.

It doesn't make the lamps any more dangerous or more safe, it just describes them according to this other action spectrum. I am not

a lawyer, I don't know if that gives people any more ammunition, but we don't feel that it would cause a big detriment to the industry.

As Don was saying, changing the action spectrum and the dose would increase the dose that the people receive, we would say that, no, in fact, it is going to lower the doses. Some of the information he presented on the label, we think it is getting too long, and if salons want to use an informed consent, we highly recommend that, and I think that is where that kind of information belongs.

Lastly, I just want to make a comment about his slides he showed about eyewear. He was I think trying to say that some of the fluorescent lamps are also a problem in the visible region, but when you are talking about retinal hazards, the geometry is really more important than the actual output of the lamps itself.

You can't just look at the output of a fluorescent lamp and compare it to a high pressure lamp and say, well, this is higher, therefore, it is more of a hazard because the geometry is a much more important factor in that case.

That is all I have to say.

DR. ROTHENBERG: Does this committee have questions for Sharon Miller or also any of our previous presenters? Yes, Jim.

DR. PLATNER: Just a real quick one for Sharon. This is regarding the definition of the manufacturer. It wasn't clear to me from what we received that that included importers.

MS. MILLER: I think the intention is for that to include everybody who wants to market their products in the United States. I am glad you brought that up because I wanted to also say something about that.

It is true we do not want salon owners to have to generate a lot of paperwork needlessly, and I feel that the way the language is written, it says that if the modification affects any aspects that are specified by the standards, so if it affects the timer, if it has any effect on the warning label or the instructions for use, things like that, then, they would have to recertify the product, but simple things like changing sockets and mechanical issues are not going to be--the way the standard is written, it would not be considered something that would rise to the level of requiring them to submit a lot of paperwork.

DR. ROTHENBERG: Michele.

CDR LOSCOCCO: Just one quick one. Any confusion that might come about from this X/Y ratio versus how it is now, that would pan out during this period of time where you have to do a market evaluation?

MS. MILLER: Yes. It may be difficult making the transition. The way it is done now is each manufacturer of the lamp, like I said, will publish a list of compatible lamps to theirs, so we are hoping that as new lamps are coming into production with the new code, it can be somehow merged with these old lists and eventually, the lamps expire, that problem will take care of itself.

Should I put the six proposals up again? Are you ready to, do you think, make any decision?

MR. KACZMAREK: If there is no more questions.

DR. ROTHENBERG: Are there questions? Yes, John.

DR. CARDARELLI: Just one brief question regarding a comment made about putting labels in publications and catalogs, and things of that nature. What was the basis behind making such a

recommendation?

MS. MILLER: Our real intention was mostly to protect the person who buys it for home use. You have probably seen catalogs that you usually get on an airplane that sell sunbed products for home use, and it is really the home user that we are trying to protect in that case.

As I said, that requirement is also in the laser standard, which probably even more so than the sunlamp area, doesn't affect individual consumers as much, but I think, I think it was Rick Mattoon, had a good point, and that is something we might want to change, only require it in advertising targeted at individual consumers, and not necessarily at salon owners, because they all know that this warning label exists. We just don't want someone buying it and not knowing that there are risks involved.

DR. ROTHENBERG: Anyone else from the committee?

MR. SMITH: A brief response.

MS. MILLER: In rebuttal?

DR. ROTHENBERG: Brief. The question that I would like to suggest that you ask Ms. Miller before you get into vote, is since I presented hard

data showing that the impact of changing from the existing action spectrum that served us well for 18 years, to the CIE action spectrum, because of the weighting and the calculation nanometer, will be adverse. It will adversely affect the health of the American people who choose to tan, and I showed you documentation on that from studies.

It seems to me that the question you should be asking of Ms. Miller, if FDA has studies to substantiate this, studies showing the impact of the X/Y system. That is the question, because if you are going to insist on this, those of us that tan people for a living know that you can't put people in for 17 or 20 minutes in a 10-minute bed. That is just plain fact of life.

So, if you do that, then perhaps we have to talk about how do we indemnify the industry from the adverse effects that this may have.

MS. MILLER: Well, I still think there must be a misunderstanding on Don's part because the goal, as I have shown, is that the dose would actually be lower now with the new action spectrum and the new definition of MED, therefore, a bed that was once a 17-minute bed, might turn out to be a 16-minute bed now.

There is no way that it can increase with using a lower effective total dose for the timer. I think he is basing his calculations on comparing the old MED to the new MED, which is 156 to 200, and not looking at the 600 versus 624. We are certainly not trying to increase the dose to the public.

As far as asking for a study on the X/Y system, obviously, we are never going to have an action spectrum for cancer in humans, so we can't really test this action spectrum out on people and say yes, this is working, this is protecting people.

But we know that in animals, it is an accurate action spectrum for squamous cell carcinoma, and we feel that it provides extra protection since we are using both erythema, which is how the current system relies upon, and the non-melanoma skin cancer action spectrum that we are actually increasing the long-term safety of the products.

DR. LAMBETH: Would you mind putting the two action spectra back up?

MS. MILLER: There, they are shown on a log scale. The pink one is the non-melanoma skin

cancer action spectrum. You can see that in the region below 300, the erythema action spectrum is higher, but then there is another difference around the 330 nanometers where the erythema action spectrum is higher than the non-melanoma skin cancer action spectrum.

I don't know if Janusz Beer wants to say anything about this. He has been a little bit more intimately involved with the development of this action spectrum than I have.

DR. LAMBETH: So, is the argument here that below 300 nanometers, that because--let me just refer to it as the purple curve--is much lower, in fact, it is a factor of 100 lower, right? That is a log scale.

MS. MILLER: Right.

DR. LAMBETH: That in the weighting process, it is not being counted as much as being a problem?

MS. MILLER: Do you want to answer that?

DR. BEER: I can try to add a few things to this information that you see on this graph. The erythema actually is a spectrum below 300 as was proposed in a straight line, because there was uncertainty in this area.

The non-melanoma skin cancer action spectrum is based on experimental points, so it was easier to develop this action spectrum in the low wavelength region.

Now, the two action spectra, as you can see, are similar, and the bottom thing is that 300 mm UV radiation does not penetrate very deeply into the skin. As a matter of fact, most of this radiation is absorbed in the stratum corneum, so this part of the action spectrum is not very critical for establishing the safety.

MS. MILLER: Yes, I was going to say the same thing, that it is really the fact that the transmission of skin is not very high in that region. That is why this animal data--not animal data, it is animal data that has been adjusted to human skin--is lower in this region, and the erythema action spectrum was a simplified version of experimental data that was developed on humans.

DR. LAMBETH: So, there is no denying that if the very high energy wavelengths were to get through the skin, that they would be harmful. It is just that the skin represents a filter to prevent that from getting in--

MS. MILLER: I think that is true.

DR. LAMBETH: That is your argument, right?

MS. MILLER: We think that by using both, that we are able to protect the public against burns and also keep similar lamps that have similar long-term effects being repeatedly used in products, so that we are not changing the long-term effects substantially when the lamps are changed.

DR. ROTHENBERG: Dr. Caswell.

DR. CASWELL: What effect does the acrylic have on the spectrum that the user receives in the tanning?

MS. MILLER: Yes, it will definitely have an effect. As far as I know, most acrylics start transmitting around 270 nanometers, so anything below that is probably not getting to the user. There are some sunbeds that don't have acrylics, it is very rare, but especially in the upper canopy, they may not have an acrylic. In that case, you would have the concern of the lower wavelength.

As I think Joe Schuster or someone mentioned, as the acrylic ages, the transmittance even starts shifting further into the longer wavelength. The acrylic definitely will have an effect on what the user receives.

MS. KANTNER: If you could just refresh on what area of the wavelength here that we are targeting, you said that was between or below 300? On the spectrum I guess of the lamps, I thought I saw a different chart. I am trying to determine on the wavelength region here, is that 270?

MS. MILLER: You mean the lower?

MS. KANTNER: Yes.

MS. MILLER: It starts at 250 and it goes out to 400, for 10 it is actually shown, but the spectrum stops at 400.

MS. KANTNER: So, if I may, maybe use this laser pointer. So, at 270, you are saying with the acrylic, where mostly this region here is not of importance or absorbed?

MS. MILLER: It would be absorbed by the acrylic.

MS. KANTNER: By the acrylic. So, in this region, at 270 up to this region, is this the area that is emitted by these bulbs?

MS. MILLER: Out into the visible also.

MS. KANTNER: Okay, so up into this region.

MS. MILLER: And it keeps going. There is even some infrared emitted by the lamps, but as far

as the biological effects, this is the region of most interest to the skin.

MS. KANTNER: Thank you.

DR. ROTHENBERG: Any other questions? If not, could we go back to that list then and let's consider the different requests. I think there is enough discussion that we should consider these one at a time rather than as a group.

MS. MILLER: Do you need me to go back and show each detailed slide or not?

DR. ROTHENBERG: Well, we have these in front of us, so if we just go to page 4, the bottom slide, Proposed Revised Label.

Any comments that anyone on the committee wants to make?

DR. LIPOTI: To me, the most important piece of information that I got today was from what Howard Cyr said, and that is that the body that determines what is a known cause of cancer, the Toxicology Institute, has classified ultraviolet radiation a known cause of cancer.

It was not on any of the slides, it was not in any of the presentations, but that is an extremely important fact that I don't think the FDA, as another body of government, can ignore that

classification.

Therefore, I would make a motion that the warning label be changed to say, "Ultraviolet radiation is known to cause" and continue on as written.

MS. MILLER: Howard is not here. I was going to refer to him. I would agree ultraviolet radiation has been shown to cause skin cancer, but I would say that the jury is probably still out on whether ultraviolet radiation from sunlamps can cause at least melanoma. Probably you could assume that it will cause squamous cell given the right circumstances, but I think it is not a proven fact that sunlamp exposure will cause skin cancer in everyone.

DR. LIPOTI: But the warning label specifically says ultraviolet radiation, it doesn't say sunlamps. So, therefore, to properly characterize what the Toxicology group has done, I am using the exact term, "known cause of cancer," so I am saying is known to.

MS. MILLER: Yes, I think what we probably should do before changing the language is look to what is done in the tobacco industry, because I believe that they also use the language "may

cause," and there may be some compelling reason to do that, and I think if it is done for cigarettes, we probably can't make a stronger statement on sunlamps.

Howard, we have a comment on given the NTP's recent publication, we should change the warning label to say "Ultraviolet radiation is known to cause skin cancer" blah-blah-blah. Do you have an answer for that?

DR. BEER: [Off mike.] I would simply say causes.

MS. MILLER: Simple.

DR. LIPOTI: I can live with that.

MS. MILLER: We will definitely consider that.

DR. ROTHENBERG: I have one question I am not clear on. One of the reasons we changed or you are proposing to change from Danger to Warning was for the harmonization. What does changing these other wordings have to do with harmonization? I am not clear, what is part of an agreement with the other organizations, the international organizations, and what is not.

MS. MILLER: I would say the entire label, as you see it there, is a reproduction of what is

in the international standard except for the Consult your Physician phrase, that is not in the international standard.

The language in the international standard was developed with our participation using the information that we have in our current standard and with the intent of shortening it and simplifying the warning.

As far as using Danger or Warning, they use Danger right now. If the committee feels strongly that the word Warning should be there, we could present that to them at our next meeting in April of 2004.

DR. CYR: Tom was suggesting that I amplify a little bit more on what the NTP report was. It's a Report to Congress, and they did look at all sorts of data involving sunlamps and skin cancer, but it was older sunlamps or different kinds of sunlamps.

They are sunlamps that were used at home, sunlamps that gave severe burns, and things like that, so it not the controlled, modern-day sunlamp system that we are dealing with here exclusively. The data has complications in it.

The other thing is that they have made

that assertion of known cause, but they said nothing about the magnitude of the risk, and they explicitly left the determination of how much actual risk was involved with sunlamps as they are used now. They leave that up to the various agencies like FDA to go ahead and do their own risk assessment.

As I said, there are other groups that don't agree with the NTP conclusion. They thought that it shouldn't have been quite as strong as it was.

DR. LIPOTI: Are there other government agencies that don't agree with the NTP?

DR. CYR: I am not sure that too many other government agencies have a major stake in this. I mean EPA has to a certain extent in activities involving ultraviolet, but this was a comment on sunlamps per se. I think we are the key players here.

I have tried repeatedly and unsuccessfully to talk to NTP and have done it very recently because I want to discuss these things in great detail. I wasn't there when the decision was made, and there are obviously many issues that I would like to clarify and get some more information on.

I have found out within the last day that I would be successful in my attempts, and so hopefully, within a couple or three weeks maybe I will better understand where NTP is coming from, and they will understand better where we are.

MR. KACZMAREK: Joe, did you want to say something?

MR. LEVY: Yes, thank you.

I think if you also look at the document, the NTP document, that does not take into account dosage at all, which makes it about--I would like to say this. I would like to say that to say that UV light is a carcinogen and therefore should be avoided is akin to saying that water causes drowning and therefore should be avoided.

It's a mischaracterization of the relationship, and this document seemed to foster that since dose was not taken into account at all, and as Howard mentioned, it doesn't take into account the equipment we use today versus what was used in the studies that they looked at, which had divergent conclusions with some of the work that CDRH has done.

DR. ROTHENBERG: Dr. Mabuchi.

DR. MABUCHI: The International Agency on

Research for Cancer has a series of monographs classifying carcinogens into established or potential, et cetera. There are two monographs on the UV radiation. I don't know what wording they use, but I guess may look at that and see what they say about the definition.

MS. MILLER: We have seen those documents. I can't tell you right now exactly what the language is, but we have looked at those, and I believe it is very similar to what has been adopted in IEC, because the people on that committee also referred to those documents in their work.

You don't have enough copies? IARC International.

DR. BEER: I took part in the development of this document, as a matter of fact, 11 years ago. The group that developed the document recognized that UV is known to be a skin cancer-causing agent, but there was no data that would directly link sunlamps to cancer, so the wording is sunlamps--I am trying to reconstruct it--"sunlamps are probable cause of skin cancer," but everybody agreed that UV, whether it comes from the sunlamps or the sun or whatever else.

MS. MILLER: I guess it is just a question

of how the product is used and the doses involved, and it's complicated.

DR. ROTHENBERG: To get back, Dr. Lipoti has recommended that we--I am not sure now--was it that we take out the word "may"?

DR. LIPOTI: Yes, I accepted a friendly amendment to say, "Ultraviolet radiation causes."

DR. ROTHENBERG: But at one point we had "is known to cause."

DR. LIPOTI: That was my original recommendation, but Dr. Beer suggested simplifying the language.

MS. MILLER: Could I say one more thing? I think what you are getting at is you want to get the message across that ultraviolet radiation is known to cause skin cancer, but the way the label is set up right now, we have those three bullets there, injury to the eyes and skin, skin aging, and skin cancer.

At least as far as the first one, which refers to acute effects, I don't think we really have a strong of a case that it is known to cause burns, for instance, at least not in all cases.

DR. BEER: I would like to add one clarification, anything that we can change in the

current text can be communicated to the IEC and request that they change their text at the next edition. IEC has a faster cycle of changing, amending, and every four or five years, there is a new edition of this standard. We are part of this process, and we can change it.

DR. ROTHENBERG: Dr. Benson.

DR. BENSON: We had added a phrase about the protective eyewear, instead of provided, wear eyewear that is federally approved for use with sunlamps or something to that effect?

MS. MILLER: I have no problem with that. I think that is a good idea.

MS. KANTNER: I think there was also some discussion about expanding on the, "Consult a physician or dermatologist," I think would be something that we would want to consider on expanding on the label, possibly prior to use, possibly because of the fact maybe a dermatologist or pharmacist, I would lean to possibly a dermatologist possibly assisting and providing more information or direction.

Is there any suggestions of preferability on expanding that?

MS. MILLER: Well, we prefer to keep it as

short and simple as possible, but I think, in principle, it's a good idea to alert people that maybe they should see a dermatologist if they have specific questions.

However, a lot of this information, at least with regard to medicines and photosensitivity, is widely available, and I think most physicians should be aware of the PDR, and that is where the information is. So, it's not inconceivable that a primary care physician could advise people on which medications might be photosensitizing.

That is a very kind of gray area. There isn't a lot of data on the numbers of people that will be affected by medicines. It is usually very low. So, even if you are taking a medication that has been shown in a few cases to be photosensitizing, chances are it is not going to be photosensitizing in your case, so it is kind of a complex issue.

I know we could add the dermatologist, but I don't know if it is really gaining us much as far as the safety is concerned. What I am saying is the primary care physician should be able to provide that kind of information.

DR. CYR: An additional comment. So many of these comments have dealt with the international standards, harmonization, and, in particular, the IEC. Industry has been a member of IEC, but industry from Europe. They have no American industry representatives on there.

We discussed this at one of our meetings before and suggested, and I guess I had offered an opportunity for the American industry to participate in this. I think there is some reluctance on the part of the industry because it is sort of like they disagree so much with them right now that they perhaps didn't want to participate.

But maybe we should suggest again that the industry be a part of this IEC process and maybe some of these things can be worked out before they land here. They could deal with them directly, and we wouldn't have to be the intermediaries with issues which are IEC sort of issues.

MS. MILLER: Actually, just in the past six months, a member of a U.S. company, has been made a member of the IEC Committee, so hopefully, in the future, you will have more.

DR. PLATNER: One of the problems I have

with that is that just the cost of traveling to those meetings really is prohibitive for any consumer group or worker group or nonprofit from the U.S., so it does limit participation.

MS. MILLER: That's true. What is why it is nice that the FDA standard is more accessible to people, you know, the common person making comments because it doesn't require traveling to a meeting, you just submit your comments after the notice is published in the Federal Register.

DR. ROTHENBERG: Is there a comment?

MS. BARR: My name is Helen Barr, FDA. I just wondered if we could consider something like consult physician or product labeling. We might check with our own Colors and Cosmetics and Drug people. I believe if there is a known sensitivity with sunlight, it would be included in--you know, it's on the prescription bottle like with erythromycin and in the labeling of cosmetics, but we might want to consider that and check with our own folks.

MS. MILLER: That is a good idea. I am not sure if a huge range of products are labeled that way, but I am sure some of them do have warnings about that. Of course, that makes the

warning label longer.

MR. KACZMAREK: Sharon has to leave shortly, and we have these other points to discuss. You wanted to say something, John, but then I am wondering if we can get the committee to say whether they like this label or don't like it, or to be neutral on it and that the Agency should work on it some more before they can say whether they really like it or don't like it.

DR. CARDARELLI: Then, I will make my comments extremely brief. One, I do like the language provided by ITA especially about wearing the federally-compliant eye protection statement.

I do like the addition of unprotected eyes, and I would also add the word "skin." It is okay, in my opinion, to leave out "avoid overexposure" based upon your earlier comment, Sharon.

The other thing is I agree with Dr. Lipoti's position on addressing or strengthening the question. I would like to see some consistency with the lamp manufacturers and the warning label, and IEC, whether or not we use Danger or Warning, just consistency.

Finally, since this is being discussed, it

would be helpful, I think, for the consumer and public health interests if you would just put a bullet on here, as well, to the FDA web site where the consumer can now go and learn more by themselves, so something to consider.

MS. MILLER: Are you referring to something like that list of medications?

DR. CARDARELLI: No, I am saying for further information, see www.fda.gov, and then lead them to an FAQ, which all these issues could be addressed.

MS. MILLER: When the label first came out, there was no such thing.

DR. CARDARELLI: Yes, I understand.

DR. ROTHENBERG: I think we have got enough discussion here that maybe you should go back and review all the comments and maybe come up with a revised label.

MS. MILLER: I would just like to say one thing. If you decide to either approve what we are doing or tell us to go back to the drawing board, that this is a proposal and that once it comes out in the NPR, there is a period for comments, and we have to address each comment at that time before we come up with a final version, so those minor

things, wordsmithing can be worked out at that time.

I think, you know, we have been here several years now presenting similar things, and because of minor changes that people have, we are not making any progress, so I think, if possible, we would like to at least hear from you that this is very close to what we want and that the fine details can be worked out in that process.

MR. KACZMAREK: What she is saying, I was just going to say that, that the way it is printed out in your handout here is not necessarily the way it would appear in the Notice or Proposed Rulemaking because there would be further wordsmithing, whatever you want to call it, before we would publish it.

MS. MILLER: But we certainly would consider your comments especially regarding whether we put Danger or Warning, and we want to be consistent. I do like the recommendation of specifying that it be federally compliant eyewear, so we would include that as a change, but as far as the "may" cause and "causes," I think we still have to discuss that, but that would be something that would also be open for change after the comment

period.

MR. KACZMAREK: So, should we pass on this one and go to the next one?

DR. LIPOTI: I guess if I read the charter for what TEPRSSC does, you really just have to consult with us, we don't need to approve the wording or anything. I think you have heard our comments. We are supposed to provide advice and consultation on technical feasibility, reasonableness, and practicability of performance standards, and I think we have.

MR. KACZMAREK: Good.

DR. ROTHENBERG: Is there anyone on the committee who is not comfortable with proceeding in that fashion with regard to this first proposal with the warning label?

I think you have gotten our sense and let's now move on to the next proposal, which has to do with including the warning label into the catalogs. There was discussion and reply from you, I believe, that it was most important for the consumer rather than the salon and industry people who are already aware of this.

So, then, you would proceed with adjusting that recommendation?

MS. MILLER: Making it a subset, you know, specifying that only advertising marketed to the consumer would require that.

DR. ROTHENBERG: Can we assume that that is the sense of the committee and move on to the next proposal, which is who becomes the manufacturer issue?

What comments do people have on if we go on to the next couple of slides before Amendment 4, the two slides, that modification, what is the sense that we want to give to the people, our presenters from the FDA concerning manufacturer definition?

DR. CARDARELLI: Can I make a quick comment?

DR. ROTHENBERG: Sure.

DR. CARDARELLI: The information I learned from the presenters today was very helpful regarding this issue, and one I think of particular interest that I found was even though you might change, say, a ballast, that could change the entire output of the lamp, so right now it is all directed towards the lamp issues.

If you do change anything else that affects the lamp output, that is an issue. Someone

mentioned about specifically addressing if you change a plug here or there, as long as it doesn't effectively change the lamp output, I have no problem with that, but a ballast could. I didn't know if that was going to make a difference or not.

MS. MILLER: I feel that the way that it is worded covers that because it does say that if the modification affects any performance aspects, that there is an applicable standard in the section that you have to recertify the product, and the output would clearly be one of those significant modifications.

DR. LIPOTI: I guess that gets to my question about the timer. In one of your slides, you say, "Examples of significant modification might be increasing the maximum timer setting," but I really don't see in your standard anything to do with the timer.

When I asked you about the timer's tolerance, you said, well, no, that's in the guidance document.

MS. MILLER: Yes, I was wrong about that. Actually, the old standard does have, one of our Compliance people reminded me, that there is a 10 percent limit on the accuracy of the timer in the

current standard.

DR. LIPOTI: There is.

MS. MILLER: Yes.

DR. LIPOTI: And that would not be changed by your proposal?

MS. MILLER: Right, we would still have that in there.

DR. ROTHENBERG: So, where do we stand on the significant--is everyone happy with that wording, "significant modification?"

DR. PLATNER: I just had one question. It is still not clear to me that this would cover importers who might then relabel or label initially a product that is coming in from Taiwan or something like that.

The manufacturer is really outside of the reach of U.S. regulations, so it seems to me the importer needs to carry that burden in some way. It is not clear to me that is covered.

MS. MILLER: That is probably in a separate part of the standard that says something like any importers have to meet all of these same requirements. I mean it certainly is covered in the standard that anybody who wants to market in the U.S. has to meet the same safety requirements

and labeling requirements, so I don't think you have to worry about that being a problem.

DR. ROTHENBERG: I didn't hear any concern about that issue. It was only about specific details of what the tanning people might do in their own salons, some minor maintenance, and so on, would that make them a manufacturer, and that doesn't seem to be the case.

MR. KACZMAREK: So, the committee endorses that.

DR. ROTHENBERG: The committee endorses the basis of it.

The next one has to do with the revisions to the eyewear requirements, No. 4, including I guess the bottom of page 6 and the bottom of page 7, the two limits on the visible region.

MS. MILLER: One of them is the floor, and the other one is a cap.

DR. ROTHENBERG: Is there any comment on this?

DR. LAMBETH: I assume that in the actual document, that the criteria for measuring the transmittance bandwidth will be put into it.

MS. MILLER: Yes.

DR. LAMBETH: That is what we were talking

about earlier.

MS. MILLER: Right, I agreed to that before. We will make that a part of the record.

DR. LAMBETH: It is not just part of the luminance transmission.

MS. MILLER: But also the UV, right.

DR. LAMBETH: Part of the spectral transmittance.

DR. ROTHENBERG: Any other discussion on No. 4 with the eyewear?

The next would be the Amendments 5A and 5B where we did have significant discussion about these items. What comments do people have as we consider where to go with this?

Let's look at 5A, replacing the erythema action spectrum with the CIE reference action spectrum.

DR. LAMBETH: Before you go on, the cap on the spectral transmittance also, I understand why you were putting it in, but it seems like the whole objective there is to enable the user to see.

MS. MILLER: That's not the objective of the cap, that's the objective of the floor.

DR. LAMBETH: The visible part of the spectrum, I mean from a pragmatic standpoint, I

assume the user, if he can't see anything, he takes the darn thing off, the goggles off. That is what we really want to avoid is them taking it off.

So, having the 5 percent cap on it, your feeling is that the 5 percent really allows you to see well enough.

MS. MILLER: We had this discussion last time. I would say that our lab has tested probably just about every type of eyewear on the market, and 90 percent of them can meet the 5 percent cap with no problem.

There is just one manufacturer that I am aware of that has a product that cannot meet the cap, and obviously, this eyewear has been used for years, and no one has ever had a problem with seeing through them, so I don't think it is going to be prohibitive.

DR. LAMBETH: I am saying 5 percent, I am saying why, you know, this is a person, 550 nanometers is actually beyond the peak sensitivity of the eye, right in that region, where we can really see really well.

MS. MILLER: Around there.

DR. LAMBETH: So, it is sort of like, okay, at that point we are dealing with sunglasses

here, if there were other room lights on, right? If I put the goggles on before I get into the suntanning, I want to see as I walk across the room, and that sort of thing. I would like to have something that actually was quite transparent at 500 nanometers.

MS. MILLER: I don't think people put them on as they are walking around because most of them don't say on by themselves, they only would stay on when you were lying down, so I don't think that they put them on until they are lying in the bed, but someone else may have an argument about that.

DR. LAMBETH: I just don't understand why we are capping it at 500.

MS. MILLER: I think Joe Levy can answer that.

MR. LEVY: Most them are held on. Generally, they are put on, then, the person lies down and turns the bed on, so they are put on right before.

DR. LAMBETH: But not walking around.

MR. LEVY: It is not to say that they wouldn't be, but generally, you are probably right next to the bed, but you could be walking around with it.

DR. LAMBETH: Let me rephrase my question. I am still trying to learn. Why do I want to prevent you from being able to see at 550 nanometers when the lamps themselves are not putting out any light out there of any harmful radiation, is it just to protect?

MS. MILLER: Well, as I said before, in the typical fluorescent lamp type of bed, we don't feel that the visible light levels are harmful to the retina, but in the situation where you have a high pressure lamp that are small source sizes, and so forth, that is why we want to limit eyewear for those products, but the other, the forthen [ph] beds, eyewear for those wouldn't have to meet the 5 percent cap.

DR. LAMBETH: All right.

DR. ROTHENBERG: Wayne.

MR. MYRICK: This also pertains to eyewear. I think we need additional wording to give alternatives to a tag, possibly direct labeling on the goggles or protective eyewear, or even possibly color code, but there need to be something that could be more permanent and an alternative.

MS. MILLER: The wording could be probably

improved. My first thought was to put something on the wording, for example, do not use in high pressure beds that contain high pressure lamps, but then that doesn't give an alternative to the user, what should they, should they just not use anything.

We are trying to keep it short and yet give the information that it is not appropriate for those types of products.

MR. MYRICK: I wasn't referring to the actual wording, but an alternative to a tag that would be attached to.

MS. MILLER: I think that is a great idea, color coding, and that could hopefully be adopted by the industry, and they would be able to explain it to their users.

DR. ROTHENBERG: We could take a brief comment from the back.

MR. ENGLISH: My name is Bob English. I am a salon owner from Pennsylvania. If there is only one type of eyewear that doesn't meet this criteria, why couldn't it just say on that particular brand, "Not approved for high pressure" - period, end of the story, simple, simple for a customer to understand, simple for a salon owner to

understand, and simple for manufacturers to understand.

MS. MILLER: That's the whole intent is that eyewear that can't meet the cap would have that label on there, so I think we are saying the same thing basically.

DR. ROTHENBERG: I think we have addressed that concern. Can we go ahead then with No. 5A, the question of the action spectrum. Yes.

DR. CARDARELLI: One thing, it is more of I guess a recommendation because this is just mainly a proposal that will go out for further comment, is that we engage also in some discussion with the American Conference of Government Industrial Hygienists who also have threshold limit values, and use a spectrum. I am not exactly sure if it's the same exact one that you are proposing to change to, or if it is the version you are changing away from.

MS. MILLER: It is neither actually. It is the spectrum that the ACGIH uses is probably closer to the non-melanoma skin cancer action spectrum, but it is not identical.

DR. CARDARELLI: Okay. So, there might be some issues, if we are going to go to the

harmonization issue, not only international, but we ought to engage our scientific associations here in America, and ACGIH would probably be a good place to start.

MS. MILLER: I don't know if you are familiar with Dr. David Sliney [ph], who has been probably you could say he was the father of the ACGIH action spectrum, he has been working with us very closely at least developing standards, and he has had a lot of input to the CIE Committee who approved these action spectra.

DR. CARDARELLI: That is good to hear.

DR. ROTHENBERG: Is everybody happy with that, seek some further interaction before making a final decision?

MR. KACZMAREK: Should we go ahead and replace "currently used" with the internationally accepted CIA reference action spectra? Yes?

DR. ROTHENBERG: How many are in favor of the proposal? How many opposed? I am going to abstain. I am still confused.

DR. CARDARELLI: I abstain.

DR. ROTHENBERG: It seems like the majority of the committee says to replace. There is also some guidance to maybe have some further

discussions before making a final decision.

MR. KACZMAREK: It will be published for comment.

DR. ROTHENBERG: Part B of No. 5, I guess use the new definition 200 joules per square meter, then, go to 3, so that the maximum will be 600, which would be similar to the 624 effective.

MS. MILLER: Right, actually, a little lower.

DR. ROTHENBERG: Basically, you want to retain an equivalent.

MS. MILLER: Yes, that's what we were trying to do. It's equivalent dose really, biologically effective dose.

DR. LAMBETH: I guess the question that comes out of this being equivalent, is there any evidence that would say that there are any currently manufactured beds which would not be satisfying the new requirement?

MS. MILLER: Since they are so similar, there is a limit on the measurement process as far as accuracy goes, I can't see that any products that meet the current 4 MED could not also meet the new 3 MED.

DR. LAMBETH: One of the arguments is from

the standpoint that the old system is a little simpler to actually characterize, so if I satisfy the old system, do I satisfy the new system?

MS. MILLER: Well, it's not really any simpler, it's just a different weighting curve you are using. But, yes, that was the goal, to keep everything, so we are delivering the same biologic dose.

Actually, in our studies that we are doing currently on exposure schedules, we have found that we are using a new 3 MED value, and as you let people build up to that dose level, it allows them to get a tan without burning and yet it is also very sufficient to produce a tan.

DR. ROTHENBERG: The question seems to be if someone has an existing system, do they have to change anything, or are we just changing the definition?

MS. MILLER: No, because for one thing, when the regulation changes, it only applies to new production. Also, biologically, a system that met the old definition should be able to meet the new definition.

So, if they are making, you know, a certain bed, they shouldn't have to change anything

on it.

DR. LAMBETH: I am a little confused about that, because it looks like they have to change the maximum limit on the timer.

MS. MILLER: The way it is calculated is changed, but the actual time that would be required to produce that dose would not change. So, you would take your measurement of the spectrum, weight it with the new action spectrum, and then calculate how much time is needed to reach a certain dose, and that dose is basically the same as it was in the old system, so the amount of time required to deliver that dose is also the same.

DR. BEER: I would like to add one piece of information. This number 200 joules per meter squared is based on experimental work done in France and in our lab, and we selected the dose that would represent the most sensitive person that could use tanning equipment, so this number is very carefully selected on the basis of hundreds of measurements.

DR. ROTHENBERG: Yes.

DR. PLATNER: I just wanted to say that it seems to me that if you take both of these amendments together, they are acceptable, at least

from my point of view, but if you only change one or the other, then, it's a problem. So, voting on them separately is a little bit awkward.

DR. ROTHENBERG: Right. So, they should be considered together.

MS. MILLER: Yes, that is why I grouped them A and B.

DR. ROTHENBERG: They should both be taken together. Is there any other comment on No. 5? I think we are then telling you to proceed.

No. 6 is the coding scheme and the X and the Y, and the reflector codes, et cetera. The reflector codes are the same or these are new?

MS. MILLER: It's kind of based on improving what is currently done. Right now there is no requirement for how the reflector design is specified. You saw the lamp that had the R on it. Since there is no industry definition of what that means, it is going to be an improvement in the system, I think, because it does make a difference on the output how the reflector is defined.

DR. ROTHENBERG: Have there been any discussions? I don't believe we had anyone here representing the lamp manufacturers.

MS. MILLER: No, but this system, which

was presented at the IEC meeting in June, was proposed by the group of lamp manufacturers, because I personally and a lot of people don't have any experience.

DR. ROTHENBERG: So, they don't see a problem--

MS. MILLER: No, this was their system actually.

DR. ROTHENBERG: --in achieving this labeling?

MS. MILLER: No.

DR. ROTHENBERG: There is a comment in the back?

MR. DUVANEY: My name is Jerry Duvaney [ph]. I work with one of the largest manufacturers of commercial tanning beds in the world. One of the things about the lamp replacement thing, nowhere do I hear anybody saying that the lamp should be tested in the piece of equipment it is intended to go into, because the tanning bed directly impacts the output of the lamp.

So, a lamp can be tested on the bench test and give totally different output when it goes in the tanning bed itself, and nowhere do I see anybody saying, hey, let's put it in the bed and

then see what the results are. That is one.

The other thing is you say it must be within plus or minus 10 percent of the original lamp. I can understand being too strong, but on the one hand, you want to put language in that says it causes skin cancer, on the other hand, you are saying but you have to give so much output, so you are kind of contradicting yourselves there, too. So, I just think we should be more uniform on this whole thing and require that the lamp be tested in the bed it is intended to go in before you say, hey, let's put a code on it. That's it.

MS. MILLER: I would just to say that we have talked about this with bed manufacturers, lamp manufacturers, state inspectors, lots of people we have had meetings, and if you really, I guess in a perfect world, you would like to test an individual lamp in any bed it could possibly be used in, but that's just not really practical, I don't think.

The theory we are operating on is that if a single lamp measured by itself in a non-reflective environment was standard procedure as far as the way it is driven, and temperature, and so forth, if it has a certain output under those conditions, and another lamp also has the

same output under those conditions, it should behave very similarly in the final product.

I think that is the best we can do as far as guaranteeing that they are going to perform the same, because, you know, the reality is the lamps have to be replaced over time and the original lamp might not be available, so you have to find a substitute that has not been tested in that specific product.

DR. ROTHENBERG: So, the concern is not really whether you take that lamp and put it in tanning bed A, it will give the same output as in tanning bed B. It is if you replace the bulb in tanning bed A, is tanning bed A going to behave the same way.

MS. MILLER: Right, and I think the answer is yes.

Then, his other comment about the plus or minus 10 percent, you know, we of course want to ensure that the replacement lamps don't create a safety problem, but we also don't want to cause a problem for salon owners, so that they will replace the lamp and it will be so much less effective than the previous lamp that the consumers will start complaining.

So, we are just trying to make sure that the performance both from the aspect of safety and tanning efficiency remains about the same.

DR. ROTHENBERG: Dr. Lipoti.

DR. LIPOTI: I do think that this does raise the importance of that SOP for lamp measurements. You mentioned that it is currently undergoing revision. I am assuming in the four years before you finally adopt the standard, it will be ready to go, but I think that is critical to the success of the regulation, it's how you determine compliance.

MS. MILLER: But as we said, that is an IEC standard and their process for revising standards is much faster. They have a meeting, someone writes it up, and it goes out for comment, and gets voted on. So, it could be less than a year.

DR. LIPOTI: I guess then that brings in the point of how do you reference the IEC standard in your regs, will you reference the most recent revision of IEC Standard 1228, or will you reference IEC Standard 1228 in effect in October of 2003.

MS. MILLER: We will have some kind of

date there that makes it clear which standard we are talking about.

MR. KACZMAREK: I think you were specifically referencing number and revision number for an IEC standard, so everybody would know which one you were talking about.

MS. MILLER: When IEC standards are published, they typically have a date or a version number or something like that.

DR. LIPOTI: Which then precludes fixing them.

MR. KACZMAREK: You would assume the process for fixing it would be pretty rapid because you are really just making a technical amendment to your reg, to update it.

DR. ROTHENBERG: With that taken under consideration, the standard procedure for testing, how many are in favor of then providing guidance to go ahead with No. 6?

[All in favor.]

DR. ROTHENBERG: Any opposed? Abstentions?

[No response.]

DR. ROTHENBERG: I guess that's it. Thank you very much for your participation and patience.

We are now a little bit behind schedule, so what I am going to recommend that we take a one-hour lunch break and try to start about 1:45.

I take it we have completed all of the public hearing part of the sunlamp issue.

CDR LOSCOCCO: I just have a question on whether we need to have a motion that says go forward with all six proposals, because we didn't really vote on the first set. Do they have to have that from us?

MR. KACZMAREK: My understanding was we were going to consider more at a time individually.

DR. ROTHENBERG: We basically concluded they should go ahead, taking into account our comments on each, so we completed all six.

We will reconvene in one hour, at approximately 1:45.

[Whereupon, at 12:40 p.m., the proceedings were recessed, to be resumed at 1:45 p.m.]

A F T E R N O O N P R O C E E D I N G S

[1:50 p.m.]

DR. ROTHENBERG: I guess we are ready to begin with the afternoon session. Dr. Tom Shope will speak on Proposed Amendments to the X-ray Standard.

Proposed Amendments to X-Ray Standard

DR. SHOPE: I am Tom Shope from the Office of Science and Technology. My purpose here today is to update the committee on the proposed amendments to the Performance Standard for Diagnostic X-ray Equipment, primarily to discuss the comments we got on our proposed rule which was published in December of 2002. The comment period ended in the spring.

I can't give you the determination on what our final proposals will be at this stage of the development process, but I can summarize the comments that we got, some of the issues that we are currently dealing with as we try to proceed to a final rule.

We haven't reached final decisions on some of the issues, so if there are suggestions that the committee would like us to consider, it is not too late for us to take those into account as we do

our final deliberations.

Just as an example of what I am going to try to cover today, a little bit of background for some of the committee that has not been involved in this, a little bit of what we got on the comments, what we are currently dealing with, then briefly when we expect to finish, talk a little bit about the role of international standards, and then entertain advice and comment from the committee.

As background, the radiological community recognized that we needed some amendments probably to the X-ray standard in the early '90s as technology and clinical use of fluoroscopic X-ray systems specifically changed quite a bit.

We saw increased radiation output capability on many systems and a lot of new imaging modes were coming into existence that really said the approach that was taken in the late '60s and early '70s, when fluoro was mainly a GI procedure, needed some additional look.

The advent of digital subtraction angiography, which was a very useful technique using fluoro equipment that resulted in considerable increase in dose from typical fluoroscopy procedures, lithotripsy systems came

along where you were using the fluoro to apply therapy.

A number of manufacturers had fluoro systems that had quite a bit of output capability due to increase in tube technology, sort of a follow-over from the CT systems, so concerns about all these kinds of issues led the Center to be concerned about these issues, as well as the rest of the community.

We had sort of a landmark conference in 1992 to talk about fluoroscopy issues in general sponsored by the American College of Radiology with FDA participation. At that conference, we had sort of a consensus that there is really a need for dose information by the fluoroscopists using these systems particularly in the interventional area.

As a result of that, we began to work on some amendments. Parallel to that, following this meeting, there was a working group that developed an International Electro-Technical Mission Standard 2-43, which deals with the safety of interventional equipment, again defined by the use of the equipment, not its physical characteristics.

Parallel to this, there was a lot of concern about radiation injuries particularly

radiation skin burns during some of the fluoroscopic procedures.

To address these issues, we began first, in 1993, we had a proposed rule typically or only to just address one aspect of equipment, and that is, we had a thing in the standard that allowed a high level control mode of fluoroscopy which, when activated, required continuous activation and it required an alarm to ring.

The exposures, however, were unlimited during this mode of operation, and we were seeing equipment with very high exposure rates, so we proposed a limit in 1993 sort of as the stop-gap or first step in this activity. That rule became final in 1995.

But as we were working on this activity, we also saw there were needs for a number of other amendments probably, and we began work on those. An Advanced Notice of Proposed Rulemaking was published in '97. We discussed concepts for our amendments with the committee in '97 and '98, and there have been some updates since then.

Unfortunately, the Y2K problem came along and some of us got rather involved in that, and sort of delayed our work on the fluoro amendments.

However, finally, in December of last year, we published the proposed rule, which I think the committee has copies of, and that was done following our estimate for development of the various impact analyses and cost and benefit estimates that were needed in order to publish a proposed rule.

The comment period ended in April, and we have been in the process of looking at these comments and trying to prepare to write the final rule since then.

Today, I want to sort of summarize what we heard in the comments and some of the things that we see perhaps that were suggested that we may need to address in the future.

We only got comments from 12 different parties, individual or organizations. You can see here the kind of individuals that we heard from. In general, the comments were supportive of our activity or generally supported the amendment process that we had proposed although there were some quibbles and some suggestions, and maybe some objections to some of the specific proposals that we put forth.

In fact, we got a lot of suggestions for

changes and things that we didn't propose. These are changes that people thought we needed to look at in addition to the things that we had proposed. One of the problems with that at this stage of the game is if we were to adopt some of those, we would need to do an additional proposal, so that everybody would know what we were talking about and have a chance to comment on it.

However, a number of the comments for changes that we didn't propose can probably be handled as the kind of changes that aren't really significant in terms of establishing new regulatory requirements. What they are doing is either clarifying definitions, making wording in the standard that is not quite clear, that we will try to make a little clearer, but there were some suggestions for significant changes that we probably cannot do at this stage without an additional proposal.

So, one of the things we will have to be doing is looking at some of those comments and seeing how they should be factored into our future work.

One of the themes that we heard from a number of the commenters was this issue of

harmonization--which is misspelled here. That is the idea of trying to make the U.S. standard not in conflict with other standards, particularly the IEC standard that many of the manufacturers are interested in, in the current environment.

You can be different than the IEC standards, but you would hope in harmonizing that you won't have requirements in the U.S. that directly conflict with something that may be required by another group.

So, what were some of the comments that we got? We got a lot of comments about modifying definitions. In fact, we had proposed a number of definition changes and additions. We got changes, suggestions on things we hadn't thought needed changing, and we probably looked through most of those and have decided in a few cases that it will make sense to make a minor change here and there.

We have added some definitions in our proposal and we have added a couple since then. I will talk a little bit more about those in a moment.

There was a desire expressed particularly by the American Association of Physicists and Medicine to have some additional consultation,

perhaps even some conference type work, with FDA, and these comments were mainly in response to some of the questions we posed in the proposed rule preamble where these were not things that we were proposing to do in this set of amendments, but ask questions about should we consider, instead of having a limit on the radiation exposure or dose rate to the patient or the input surface of the patient, should we instead focus on the dose to the image receptor, what you are really interested in, in assuring appropriate imaging performance, or should we do something on imaging performance in general, is there a way to tie that to exposure and have a rationale for exposure limits based on some kind of criteria for imaging performance.

Another issue that was suggested is that the new solid-state X-ray imaging devices that we talked about may need additional things in the way of controls or standards or measurement techniques that we didn't address in this particular standard, and the medical physics community I think is interested in working on these issues.

So, those are some of the kind of comments that you could sort of put in the category of these are future things that we are going to have to

probably take a look at, but I think there is interest in the community in working with FDA on those issues should we decide it is appropriate to go forward.

Some of the definitions that we got comments on and some of these we hadn't proposed the change, but it was pointed out that we have something called an attenuation block in our current standard. This is a piece of aluminum that is put into the X-ray beam during a testing procedure.

We specified both the size and the thickness of that block. It turns out the fluoroscopic imaging systems now have X-ray field sizes that are typically larger than our defined size of the block, so we need to make this thing bigger probably. It is probably just going to be changing, instead of 20 by 20, make it 30 by 30.

As soon as we do that, we will probably need to make it 40 by 40, but we are at least considering should we modify this definition. There is a slight quibble perhaps on the thickness. We have 3.8 centimeters, the IEC has adopted 4.0, so we need to think about that.

It is not a problem if you pass one test,

you pass the other, it's okay to be a little bit different like that, but we need to make sure that passing one test doesn't put you in conflict with the other mode of testing.

Mode of operation is one that has given us a little bit of cause for thought. We define mode of operation trying to describe the various ways a fluoro system could be operated to require information be provided to the user or to encourage manufacturers to describe what that mode was intended to do, when you should use it, those kinds of things.

Our definition of mode of operation is a little different than the definition used in the IEC standard for the similar concept. In the IEC standard they have, a mode of operation is activated by a single control, in other words, it's a one-button kind of selection that goes on there, and if you can't do it with just one button, it somehow must not be a mode of operation.

We didn't want to restrict it in our proposal when we made it to that single control mode, and I think we are still looking at those comments that we got, but we will see how that plays out. We think mode of operation shouldn't be

limited just to one control, there may be ways where selection of two ways of controlling the system, two different features might put you in a particular mode of operation.

We didn't have a definition in the standard of C-arm fluoroscopes and we are putting some requirements on those. The suggestion was made that we probably should define that, and we agreed with that.

It was suggested that we use the term "exposure" in the old, non-system international or international system of units meaning of a quantity that is no longer in favor, so we are making the change, of course, to go to air kerma or kerma as a measure, but exposure has a second meaning which means activating the X-ray tube.

The suggestion was made that maybe we ought to include that because we want to use both ways, so we are looking at probably implying that exposure also has a second meaning. It is the meaning that the IEC gives to the term "loading," which means loading up the generator and making X-rays in the X-ray tube.

A comment on the definition of isocenter, a little modification there. Some comments that

our definition of solid-state X-ray imaging device might have been a little more complicated than it needed to be, and I think we are probably going to take those comments to simplify that definition a little bit, to take out some of the prescriptive kinds of words that might somehow limit the next generation of solid-state image devices to fit the definition.

We have a question about the definition of "visible area," which I will talk a little bit more about later. Then, there were a few other definitions, so there was a number of things that we hadn't proposed that we got some comments on, and some of them probably we will go ahead and be able to deal with as not requiring additional proposals.

We also got some critiques of some of our proposed comments. I think there was a mixture of comments here. One of the concerns that seemed to concern the users of fluoro systems was that we have a suggestion that in describing the modes of operation, this is in the portion 1020.30 that deals with information to be provided to users in the users' manuals, that manufacturers describe the modes of operation, how you activate a mode and

really what the intent of that mode is.

I think some of the clinicians reacted to that as by doing this kind of labeling for the X-ray equipment, this would somehow limit their ability to use the X-ray system as they saw fit, and therefore, they weren't exactly happy with having manufacturers specify the intended use or the clinical task that a mode of operation was for.

I think we don't think that is going to limit the way users could use the equipment, so that is one of the issues that we are currently looking at is to how to make clear what we want to be in the users' information and how the user who reads this information can relate that particular mode of operation to the clinical task that I want to do with the fluoro system.

We had some comments about the manner and accuracy of dose display.

This is just a little cartoon that describes what we are currently proposing to require, and that is that the user, while they are using the fluoro system, can look up here and see a display of something related to the dose rate or the cumulative dose at a particular thing called the reference point, which is meant to be about

where the skin of the patient typically would be, but, of course, that is not a very precise thing, and this cartoon is not quite to scale.

This is meant to be the isocenter of the X-ray system, the point about which this apparatus would rotate, and the reference point is 15 centimeters toward the X-ray tube. This cartoon shows a line here, but in real life it is probably much closer to the table surface in most patients, the idea being that as this thing rotates around, this location would be an approximate indication of the kind of radiation dose, air kerma, air kerma rate reaching the patient.

So, during the procedure, the radiologist or fluoroscopist would be able to see that, see what kind of dose rates are being delivered instantaneously, and also in our proposal, once he stops the exposurer would see a cumulative number there.

Some of the comments were--well, let me just say this would illustrate I think what we were proposing in the proposal, and that is during a radiation, you would see some kind of display, where this is on a separate little panel. It is shown on the fluoro image down in the corner. We

didn't specify that sort of thing, but we were contemplating dose rate information while active fluoro was going on and a cumulative number to be shown at the cessation of exposure.

One of the comments from some of the clinicians were we would like to see this cumulative number all the time, not just at the end, so one approach to that might be something like this that would have two displays that during fluoro, active fluoro, you would see this number change and this number change. At the cessation of fluoro, this number would go away because there would be no rate, but you would have the cumulative exposure to that point during the procedure shown.

The manner of this kind of display then is something that we are currently considering how we should proceed.

Another question was what is the accuracy of this dose display information. Our proposed amendments suggested that this display be accurate to plus or minus 25 percent. We later learned, much to our chagrin, for not having checked this beforehand, that the IEC standard has requirements for display of air kerma rate, cumulative air kerma, dose area product, and those are all

specified basically with a plus or minus 50 percent accuracy.

So, one of the things we got comments on was we shouldn't use this, we should use the IEC. I think there is some concern about how useful is a plus or minus 50 percent kind of number if you are interested in trying to track patients long term, one of the concerns or one of the potential uses of this kind of dose display information, particularly the cumulative dose number, is something that could be used in the patient record or could be used in the concept of a reference dose level, which is a facility can monitor over a period of time typical numbers and be able to identify outliers, either procedures, physicians, particular equipment that are resulting in a typical dose that is higher than usual and maybe compare those with national norms if that kind of data can be collected.

So, if the number is only accurate to plus or minus 50 percent, there are questions about how useful that would be, so this is one of the issues that I think we are going to have to reach a decision on, and comments from the committee, of course, would be welcome.

We are looking at what are the various

things that could be involved in contributing to this uncertainty, what are the factors. It depends on how this number is derived, whether it is a measured or calculated or an inferred number, but I think there is some feeling that probably this is clearly doable. This is just at the borderline perhaps and we need to come to some decision on what is the best approach there.

Other requirements. A proposal that what we are really trying to do in this Section 1020.30(q)(2) was to say that users of systems can have their systems modified. In fact, if they want to get a system modified that currently exists, and they want to add a dose display, if that ever comes to be possible, they could do that to comply with our new proposed regs, and not have to worry about the kind of certifications required if this is done by the owner provided that the work that the owner has done for them doesn't lead to a noncompliance with the standard.

Some of the comments implied that we were expecting the owner, the physician or the hospital, to take responsibility technically for this modification, and I think our response is no, that is not really what we meant. We meant enter into a

contract with somebody that knows what they are doing and is part of the contract, make sure they assure you that it meet specs when they are done.

We would still hold the owner who requires this modification to be done is ultimately responsible, but he should have some fallback to the person having done this kind of a change.

There are a number of potential reasons for making these kind of upgrades to existing equipment that a current technical reading of the standard would sort of say you can't do, but we want to make it specific that we do encourage upgrading of some of these features like last image hold, dose display, perhaps even collimation changes, and this change would make sure that that is understood that that can be done.

Another thing that we had some comments on were the issue of the audible signal during fluoroscopy. We currently have a requirement that has been in our standard and was adopted in the IEC standard that came along later, a requirement that during fluoro, there is a timer that can be set any period up to five minutes.

At the expiration of that particular length of time, whatever was set, you get an

audible signal that sounds to tell the fluoroscopists that they have exceeded that amount of fluoroscopy time. That signal can be silenced by a reset and the fluoroscopy can continue.

This does not interrupt the exposure, but it just allows a reminder that this five-minute time period has expired or the four-minute, whatever they set.

We proposed in our standard that this not be something that continues to sound, but that it just sound periodically, not require a reset, and every five minutes you get another sounding of this alarm just as a reminder that that much time has passed.

We also asked the question in our preamble would it be better to have this as something that the physician using the system can set ahead of time. For instance, in many of the interventional procedures, five minutes of fluoro is a rather short time, and being bothered by the alarm going off every five minutes is more of an aggravation than a help, perhaps this ought to be 15 minutes or 20 minutes.

I think our comments came back where, no, that probably gets us into more trouble than it

would help in that people will set this for a long period of time and the next user won't realize that and they may think they are going to get a warning in five minutes and it's 20 minutes before they hear the warning.

Anyway, this is an issue that we are currently looking at. If we were to proceed with our proposal, we will have a conflict with the IE standard for X-ray generators 2-7, which prescribes exactly the requirement we currently have, so our modification would require us to work with the IEC perhaps to get them to make a similar change in the IEC standard to do away with the fixed five-minute timer that has to be manually reset if that would be the way we proceed.

We also have a question about applying the requirements for dose display and last image hold to what are referred to as mini-C-arm systems. These are the small, not necessarily portable, but they started out that way, but I think now most of them are mounted on carts, C-arm fluoro systems that have a source-to-image receptor distance of less than 45 centimeters.

These are labeled currently with a variance if they have this for extremity use only.

We had already proposed that systems that are this small can have a different source-to-skin distance requirement, but the other comment was that maybe these systems, because they are used only on extremities, they are used in situations where we are really not that concerned about dose and long procedures perhaps, that maybe this expense of a dose display and a last image hold is more expense than worth it here on these kinds of systems.

The converse argument, of course, is that these can be used for interventional procedures even perhaps if it's on an extremity surgery, those kinds of things. We don't advocate it, but these systems might occasionally be used in pediatrics.

So, there is a question of whether we should include or not include the mini-C-arms in the requirement for a dose display and last image hold feature. Most of these systems these days, in fact, are digital systems and many of them, most of them, in fact, come with last image hold, I suspect, although we haven't done a complete survey to make sure there is no system that currently doesn't have last image hold.

So, those are some of the issues that we are currently working through with regard to this

comment.

There were a number of changes suggested for things we didn't propose, and I will just briefly mention a couple of these.

One of the questions or comments we got from several folks was that it would be nice or you guys ought to require that manufacturers give information in tools to the purchaser or to the medical physicist working for the purchaser or to the repairman who comes in as a third-party servicer.

That would facilitate troubleshooting, repair service, and testing. This was the range from things that would help the serviceman to things that would help the medical physicists do acceptance testing or periodic testing.

This was not something we proposed I think to go this far. We need to thoroughly air such a requirement in a proposal first. It is also not clear that these things raise to the level of being radiation safety related directly that we could actually include in a radiation safety standard although I think people can make an argument that some of the testing is necessary and important, whether we should make it mandatory that

manufacturers provide this is still for discussion.

One of the driving forces for some of these comments has been from the service industry, the third-party service industry, that find in this day of computerized devices it is very difficult to do some of this servicing if you don't have the secret passwords and the codes to get at some of these things.

What we require in the standard is that the manufacturers have to provide to the assembler, the person who assembles the X-ray system or puts it together initially adequate information to allow that system to be assembled and tested in order to assure compliance with the standard, so that kind of information is required.

We have just had some discussions about making clear that that includes computer programs if that is the only way you can do it and that is the only way you have described it for the service person or for the assembler, but if that can be separated out, then, the manufacturer doesn't have to give anything else other than that assembly instructions to complete what is basically the manufacturing of the system.

So, we have got that kind of comment. We

had several comments raised about the specification of the voltage wave form or the kVp wave. This has to do with the fact that there are a lot of different generators. Generators have changed over the years from systems that had quite a bit of ripple in their voltage wave form to basically constant potential generators, and some of the testing procedures that we have in our standard, or that the IEC has, can be impacted by the voltage wave form that is being used for the testing.

I think we are comfortable that most of what we require is meant to be the way the system is delivered, so it's the wave form the system puts out, not any particular kind of wave form, but we are looking at this a little bit more to make sure we are on firm ground.

I think our inclination is no, we don't need to specify that, we don't need to require that that be specified.

We got a number of comments to use specific requirements from the IEC standard. The suggestion was that we use the IEC version of dose information, test procedures, and primary protective barrier test procedure and limits on the primary protective barrier transmission.

I think there are some reasons not to attempt to put this kind of thing into our standard, having to do a lot with the difference in terminology that is used in the IEC requirements compared to ours. We can't just plug them in because they use terms differently and they are defined differently.

We could do that, it would be I think somewhat confusing. We think probably we can deal with these comments without having to go that far.

There was a discussion or a suggestion from radiologists that, gee, this dose display you are talking about is great, but there is a better way to do it, and there have been some publications along these lines. One vendor actually had a system for a while that did this, and this is skin dose mapping. The idea is don't tell me just the maximum dose or, excuse me, the cumulative dose or the dose rate, show me where on the patient that dose is and how hot it is.

This was a system offered by Siemen on a previous version of their interventional X-ray system. This is basically meant to be a picture. Here is the patient lying on the table. This is their abdomen and it has been folded open here, so